DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-70

July 20, 2001

Eva K. Engler, President
Engler Engineering Corporation
1099 E. 47th Street
Hialeah, Florida 33013

Dear Ms. Engler:

During an inspection of your establishment located in Hialeah, Florida on May 15-16, 2001, FDA Investigator Victor Spanioli determined that your establishment is a manufacturer and distributor of human and veterinary dental polishers/accessories, ultrasonic scalers/accessories, and veterinary devices, which are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Federal Food, Drug, and Cosmetic Act (the Act), the products that your firm manufactures are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The above-stated inspection revealed that the devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm failed to analyze all sources of quality data to identify existing and potential causes of nonconforming product and other quality problems as required by 21 CFR 820.100(a)(1). For example, warranty claims and repair reports are not analyzed to identify systematic failure modes (FDA 483, Item #1).

Your firm's response (undated) received in our office on July 11, 2001 is inadequate because it failed to provide examples of the actual service reports and there are no remarks discussing the reason the conclusion "no further investigation" was not possible or not taken. There is no statement as to how the report was closed, e.g., replaced component, etc.

2. Your firm failed to establish and maintain procedures for implementing corrective and preventive action (CAPA) as required by 21 CFR 820.100. For example, your SOP, rev. C addressing CAPA does not include a requirement to review sources of quality data to analyze for significant trends.

Your response (undated) received in our office on July 11, 2001 is inadequate because it fails to define the term "periodically", e.g., quarterly, annually, etc. This review needs to be more specific and should describe what methodology is required to be performed to detect recurring quality problems. Further, your response is incomplete because it failed to provide any evidence of reviews that have been conducted.

3. Your firm's device history records (DHRs) are not maintained to ensure that each batch, lot or unit are manufactured in accordance with the device master record (DMR) as required by 21 CFR 820.184. For example, manufacturing records for 1000 pieces of the scaler tip, lot To501 could not be located. A new document was created on May 14, 2001 without any reference to the lost original records.

Your response (undated) received in our office on July 11, 2001 is inadequate because it fails to address any investigation that may be conducted for a lost or misplaced record and is properly documented for the file.

4. Your firm failed to approve documents that require an approval date signature of a responsible official as required by 21 CFR 820.40(a). For example, the Non-Conforming product procedure, WI:13-W01 Rev. A was not signed or dated.

Your response (undated) received in our office on July 11, 2001 appears to be adequate.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to Martyn Thomas, Electronics Engineer, at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Your firm was granted an extension to respond to the Inspectional Observations (FDA 483) on June 11, 2001 extending the response date to June 28, 2001. To date, we have not received your response and, as requested by the investigator, we have not received a copy of the cover letter for your submissions addressing premarket notifications for the dental polisher and a combination polisher and ultrasonic scaler subject to 21 CFR 872.4200 and 872.4850. Please advise whether or not you intend to submit premarket notifications for these devices or label and distribute them for veterinary use only.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Donna Kenyon

for Emma Singleton
Director, Florida District